

### DETAILED ACTION

1. This Office Action is in response to the amendment filed October 16, 2008. As directed by the amendment, claims 1-67 were cancelled, and claims 68-90 have been added. Thus, claims 68-90 are pending in this application.

#### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 68-70, 73, and 75-88 & 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robertson et al (EP 1075848 A2) and further in view of Goldstein (6,012,455).

Robertson discloses a mouthpiece (figure 8) for the delivery of gases to a user, comprising: an outer flap (300 of figure 9) adapted to conform to the user's mouth, providing a substantial seal about the outside of the user's mouth and capable of delivering gases to the user's oral passage (via apertures in 300); an elbow connector (45 of figure 1 and [0025]-[0026]), capable of receiving said gases (figure 1), in fluid connection with said outer flap ([0030]); however, Robertson lacks the nasal cannula sealing in each of the nares of the user and capable of delivering gases to the user's nares, said nasal cannula attached to one of said outer flap and said elbow connector.

Goldstein teaches a mouthpiece with a nasal cannula (figure 14) which is useful as an air delivery apparatus that uses a mouthpiece (92) to stabilize the air delivery

apparatus to provide a good air seal. The air delivery apparatus taught by Goldstein uses a nasal cannula that seals in each of the nares of the user and is capable of delivering gases to the user's nares and the said nasal cannula is taught to be attached to a mouthpiece and could be quickly and easily attached to the elbow connector disclosed by Robertson.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the mouthpiece and air delivery apparatus disclosed by Robertson, by utilizing a nasal cannula that delivers gas to a users nasal passage in order to provide a gas delivery apparatus that delivers breathing gas to a users nasal passages because it is "almost universally adopted based on the well known observation that humans show a decided preference for nasal breathing during sleep." See: Robertson [0002].

Regarding claim 69 Robertson discloses an elbow connector (45) is substantially L-shaped [0025], and Goldstein teaches a nasal cannula that could quickly and easily connect to one end of the L-shaped elbow connector (45) and the outer flap (300 of Robertson), and Robertson discloses the other end of the L-shaped nasal connector (45) that is adapted to receive said gases for delivery to the user. See: figure 1 of Robertson.

Regarding claim 70, Robertson discloses an elbow connector that includes a swivelable joint ([0025] of Robertson) that would allow said elbow connector (45 of Robertson) to swivel relative to the nasal cannula (figures 18 & 21-22 of Goldstein) and said outer flap (300 of Robertson).

Regarding claim 75, Goldstein teaches a nasal cannula that includes an extension mechanism (100 & 102 and col. 5, lines 38-43) that would allow the nasal cannula to adjustably extend from the elbow connector (45 of Robertson) or said outer flap (300 of Robertson).

Regarding claim 76, Goldstein teaches the extension mechanism as a series of bellow-like corrugations (figure 14) on the nasal cannula that allows the length of said nasal cannula to be adjusted. See: col. 5, lines 38-43.

Regarding claim 77, Goldstein teaches a nasal cannula that comprises a pair of nasal prongs (pair of tubes entering nasal passages of user in figure 14).

Regarding claim 78, the nasal cannula taught by Goldstein is capable of detaching (via disconnecting tubes) from the elbow connector (45 of Robertson) and/or the said outer flap (300 of Robertson), which would allow for different sized nasal cannula to be connected to the said elbow connector (45 of Robertson) and/or the outer flap (300 of Robertson).

Regarding claims 79 & 83, Robertson discloses forming a mouthpiece made of silicone [0026] and it would have been obvious to one having ordinary skill in the art to have formed the entire airway device taught by the combined references of the same material because it has been held that the selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Regarding claim 80, Robertson discloses an outer flap (300) that has a lip ((306) [0030] or (61) [0020]) extending around its perimeter to assist in sealing of said outer flap against the user's face.

Regarding claim 81, Robertson discloses an outer flap (300) that includes a tubular passageway (304) extending through said outer flap and the tubular passageway (304) in fluid communication (via apertures 302-304) the elbow connector (45) to deliver gases from said elbow connector to the user's mouth (figure 8). See: [0030].

Regarding claim 82, Robertson discloses a tubular passageway (304) that contains two outlets (302 & 303) to direct gases flow around the sides of the user's mouth as gases flow out of said tubular passageway and into the user's mouth.

Regarding claim 84, Robertson discloses a mouthpiece (102 of figure 8) with a vestibular shield (112 of figure 8) connected to the tubular passageway and the vestibular shield is disposed in a user's mouth vestibule. See: figure 8.

Regarding claim 85, Robertson discloses a mouthpiece (102 of Robertson) with an outer flap (300 of Robertson) adapted to conform to the user's mouth (figure 8 of Robertson), providing a substantial seal about the outside of the user's mouth and capable of delivering gases to the user's oral passage; an elbow connector (45 of Robertson) capable of receiving said gases, in fluid connection with said outer flap (300 of Robertson); and Goldstein discloses a nasal cannula (figure 14) sealing in each of the nares of the user and capable of delivering gases to the user's nares and it would be obvious to connect the nasal cannula to either the outer flap (300 of Robertson) and/or

the elbow connector (45 of Robertson) by utilizing the nasal cannula extension mechanism (expandable and contractible tubes 100 & 102 of Goldstein) to allow the nasal cannula to adjustably extend from either/or the elbow connector (45 of Goldstein) and/or the outer flap (300 of Robertson).

Regarding claim 86, Goldstein teaches a nasal cannula extension mechanism (tubes 100 & 102 of Goldstein) that are bellow-like corrugations (figure 14 & col. 5, lines 38-43) in the nasal cannula that allows the length of the nasal cannula to be adjusted.

Regarding claim 87, the nasal cannula taught by Goldstein is capable of detaching (via disconnecting tubes) from the elbow connector (45 of Robertson) and/or the said outer flap (300 of Robertson), which would allow for different sized nasal cannula to be connected to the said elbow connector (45 of Robertson) and/or the outer flap (300 of Robertson).

Regarding claim 88, Robertson discloses a mouthpiece (102 of Robertson) for the delivery of gases to a user (figure 8), with an outer flap (300) adapted to conform to the user's mouth, providing a substantial seal about the outside of the user's mouth and capable of delivering gases to the user's oral passage; Robertson also discloses an elbow connector (45 of Robertson), capable of receiving said gases, in fluid connection with said outer flap (300); and Goldstein teaches a mouthpiece with a nasal cannula (figure 14) wherein the a nasal cannula (figure 14) seals in each of the nares of the user and is capable of delivering gases to the user's nares, the nasal cannula can be quickly and easily attached to either/or the outer flap (300 or Robertson) and/or the elbow connector (45 of Robertson) and the elbow connector (45 of Robertson) disclosed by

Robertson has a swivelable joint [0025] which would allow the elbow connector (45 of Robertson) to swivel relative to said nasal cannula (figures 14, 18, & 20-22 of Goldstein) and/or said outer flap (300 of Robertson).

Regarding claim 90, Robertson discloses a mouthpiece (102) for the delivery of gases to a user, comprising: an outer flap (300) adapted to conform to the user's mouth, (figure 8) providing a substantial seal about the outside of the user's mouth and capable of delivering gases to the user's oral passage. Robertson also discloses an elbow connector (45), capable of receiving said gases, and in fluid connection with said outer flap (via apertures 302-304) and Goldstein teaches a nasal cannula (figure 14) sealing in each of the nares of the user and capable of delivering gases to the user's nares, said nasal cannula can be releasably attached to the outer flap (300 of Robertson) and/or the elbow connector (45 of Robertson) so that different sized nasal cannula can be connected to the elbow connector (45 of Robertson) and/or said outer flap (300 of Robertson).

4. Claims 71 and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robertson et al (EP 1075848 A2) in view of Goldstein (6,012,455) and further in view of Daniell et al., (EP 0845277 A2).

The combined references disclose all the limitations of claims 71 & 89 except the elbow connector having an outlet vent to allow diffusion of the user's exhaled gas.

Daniell teaches a swivel type elbow connection with an outlet vent (37 of figure 8) that allows a patient to exhale through the nasal passage or through the mouth. See: col. 8, lines 22-45.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have substituted the swivel elbow connector disclosed by Robertson with the swivel elbow connector with an outlet, as taught by Daniell in order to obtain a gas delivery apparatus that would allow a patient to exhale either through the nasal passageway and/or the mouth based upon the patient's individual breathing habits or desires.

5. Claims 72-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robertson et al (EP 1075848 A2) in view of Goldstein (6,012,455) in view of Daniell et al., (EP 0845277 A2) and further in view of Ging et al., (2003/0196662).

The combined references disclose all the limitations of claim 72 except an elbow connector comprises a plurality of apertures in the apex of the L-shape of the elbow connector with the apertures adapted to vent gases exhaled from the user.

Ging teaches an elbow connection (360) assembly with a vent cover (figures 20-22d) that have a plurality of apertures (390) in the apex of an L-shape of the elbow connector and the apertures adapted to vent gases exhaled from the user. See: figures 20-22d and [0166].

It would have been obvious to one having ordinary skill in the art at the time the invention was made to used a plurality of outlet apertures, as taught by Ging, instead of a single outlet aperture, as disclosed by Daniell in order to form a gas delivery device that allows a patient to exhale either through the nasal passageway and/or the mouth based upon the patient's individual breathing habits or desires that would continue to function even if one of the apertures becomes blocked or closed.

Regarding claim 73, Ging teaches an elbow connector (360) that has an outlet vent comprised of a plurality of apertures in the shape of ovals (figure 21) squares (figure 22) and circles (figure 22d) which would allow diffusion of the user's exhaled gases and it would have been obvious to one having ordinary skill in the art to have formed elongate and tapered apertures so as to be larger proximal to said swivelable joint and narrower distal to said joint, as it has been held that a change in the shape of a prior art device is a design consideration within the skill of the art. In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

Regarding claim 74, Ging teaches an elbow connector that has a ledge (figures 20-22d) formed by a reduction in the diameter of said elbow connector and the reduction of the diameter of the elbow would be formed distal to said swivelable joint (45 of Robertson) with the plurality of apertures (390 of Ging) formed on the ledge to diffuse gases exhaled by the user. See: figures 20-22d of Ging and [0166].

6. Applicant's arguments with respect to claims 58-67 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Goldstein 4,752,510; Thornton (6,405,729); Robertson et al. (2003/0089371); and Barnett et al. (2002/0043265) which all teach patient interface devices and connections thereof.



8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/  
Examiner, Art Unit 3771

/Justine R Yu/  
Supervisory Patent Examiner, Art Unit 3771